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EXAMINER

WARE, TODD

ART UNIT

PAPER NUMBER

1615

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16

Please find below and/or attached an Office communication concerning this application or proceeding.



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GRANT 2000

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Paper No. 16

Application Number: 09/538,829
Filing Date: March 30, 2000
Appellant(s): MODI, PANKAJ

Debra Anderson Reg. No. 44,506
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 3-21-02.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is incorrect. A correct statement of the status of the claims is as follows:

This appeal involves claims 26-27, 29, and 37.

Claims 28, 30-34 and 36 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) *Issues*

The appellant's statement of the issues in the brief is correct.

(8) *Claims Appealed*

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) *Prior Art of Record*

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5,049,389

Radhakrishnan

9-1991

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

A. Claims 26-27 and 37 are rejected under 35 U.S.C. 102(e) as being anticipated by Manning et al (5,770,559; hereafter '559).

'559 discloses pulmonary aerosols comprising insulin micelles that are administered with a metered dose inhaler (C 10, L34-44; Examples 4 and 13). '559 does not specifically state buccal administration of the disclosed compositions, however it is submitted that inhalation of the composition of '559 through the mouth would inherently result in buccal administration of the composition.

(11) Response to Argument

Appellant argues that the instant claims are not anticipated over Manning since the instant claims require buccal administration of an effective dose of insulin while the Manning requires administration of the compositions to the lungs through inhalation. Applicant further argues that since Manning requires the effective dose to be made available through the lungs, it can not anticipate the instant claims. However, this argument is not found persuasive. Manning sets forth administration by the mouth to the lungs with a metered dose inhaler. In order for the composition to arrive in the lungs, it must first be administered to the mouth and traversing therein to arrive in the

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lungs. Therefore, the requirement of buccal administration is met, since buccal administration only means that the composition is administered to the mouth.

Appellant's argument that an effective dose is not delivered to the mouth is also not found persuasive. The definition of "effective dose" was first raised in the "non-final" Office Action of Paper Number 5, mailed 3-13-91. At that time, it was submitted that the phrase was indefinite under 35 U.S.C. 112, second paragraph, since the claims did not define what the effective amount was to accomplish. The reply of paper number 6, 4-27-01, set forth that this phrase was not indefinite since the specification provides guidance on how to mix various amounts of insulin with the micelle formulation. While recognizing that instant claims 26 and 37 do not require a micelle formulation, that rejection under 35 U.S.C. 112, second paragraph was not maintained. The claims were then given their broadest reasonable interpretation and examined in accordance with MPEP 2111. Therefore, it is the position of the examiner that the art of record meets this limitation since any result would suffice and the method of the art would result in wetting the mucosal cavity.

(12) Grounds of Rejection

B. Claims 26-27, 29, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manning et al (5,770,559; hereafter '559).

'559 teaches pulmonary aerosols comprising insulin micelles that are administered with a metered dose inhaler (C 10, L34-44; Examples 4 and 13). '559 does not specifically state buccal administration of the disclosed compositions, however

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it is submitted that inhalation of the composition of '559 through the mouth would inherently result in buccal administration of the composition.

(13) *Response to Argument*

Appellant argues that the instant claims are not obvious over Manning since the instant claims require buccal administration of an effective dose of insulin while the art of record requires administration of the compositions to the lungs through inhalation. Applicant further argues that since the art requires the effective dose to be made available through the lungs, the art effectively teaches away from the instant claims. However, this argument is not found persuasive. Manning sets forth administration by the mouth to the lungs with a metered dose inhaler. In order for the composition to arrive in the lungs, it must first be administered to the mouth and traversing therein to arrive in the lungs. Therefore, the requirement of buccal administration is met, since buccal administration only means that the composition is administered to the mouth. Appellant's argument that an effective dose is not delivered to the mouth is also not found persuasive. The definition of "effective dose" was first raised in the "non-final" Office Action of Paper Number 5, mailed 3-13-91. At that time, it was submitted that the phrase was indefinite under 35 U.S.C. 112, second paragraph, since the claims did not define what the effective amount was to accomplish. The reply of paper number 6, 4-27-01, set forth that this phrase was not indefinite since the specification provides guidance on how to mix various amounts of insulin with the micelle formulation. While recognizing that instant claims 26 and 37 do not require a micelle formulation, that

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rejection under 35 U.S.C. 112, second paragraph was not maintained. The claims were then given their broadest reasonable interpretation and examined in accordance with MPEP 2111. Therefore, it is the position of the examiner that the art of record meets this limitation since any result would suffice and the method of the art would result in wetting the mucosal cavity.

(14) Grounds of Rejection

C. Claims 26-27, 29, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Radhakrishnan (5,049,389; hereafter '389).

'389 teaches pulmonary administration of insulin containing micelles by means of a metered dose inhaler. The instant claims require buccal administration of the composition. '389 does not specifically state that the is administered buccally, however it is submitted that inhalation of the composition of '389 through the mouth would inherently result in buccal administration of the composition.

(15) Response to Argument

Appellant argues that the instant claims are not obvious over Radhakrishnan since the instant claims require buccal administration of an effective dose of insulin while the art of record requires administration of the compositions to the lungs through inhalation. Applicant further argues that since the art requires the effective dose to be made available through the lungs, the art effectively teaches away from the instant claims. However, this argument is not found persuasive. Radhakrishnan both sets forth

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administration by the mouth to the lungs with a metered dose inhaler. In order for the composition to arrive in the lungs, it must first be administered to the mouth and traversing therein to arrive in the lungs. Therefore, the requirement of buccal administration is met, since buccal administration only means that the composition is administered to the mouth.

Appellant's argument that an effective dose is not delivered to the mouth is also not found persuasive. The definition of "effective dose" was first raised in the "non-final" Office Action of Paper Number 5, mailed 3-13-91. At that time, it was submitted that the phrase was indefinite under 35 U.S.C. 112, second paragraph, since the claims did not define what the effective amount was to accomplish. The reply of paper number 6, 4-27-01, set forth that this phrase was not indefinite since the specification provides guidance on how to mix various amounts of insulin with the micelle formulation. While recognizing that instant claims 26 and 37 do not require a micelle formulation, that rejection under 35 U.S.C. 112, second paragraph was not maintained. The claims were then given their broadest reasonable interpretation and examined in accordance with MPEP 2111. Therefore, it is the position of the examiner that the art of record meets this limitation since any result would suffice and the method of the art would result in wetting the mucosal cavity.

For the above reasons, it is believed that the rejections should be sustained.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on M-F, 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Respectfully submitted,

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Todd D. Ware
June 3, 2002

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